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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/696,174	10/29/2003	Swaminathan Jayaraman	795-A03-004	7393

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EXAMINER	
GHERBI, SUZETTE JAIME J	
ART UNIT	**PAPER NUMBER**
3738	

DATE MAILED: 12/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/696,174	JAYARAMAN, SWAMINATHAN	
	Examiner	Art Unit	
	Suzette J. Gherbi	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 October 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,8,9,11,13,16,28 and 34-51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,8,9,11,13,16,28 and 34-51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *definition copies*.

DETAILED ACTION

1. Applicant's amendment dated 10/3/05 has been received in application serial number 10/696,174. claims 2-7, 10, 12, 14-15, 17-27 and 29-33.

Response to Arguments

2. Applicant's arguments with respect to the claims and the Francis et al. patent 6,524,795 have been considered but are moot in view of the new ground(s) of rejection.

Specification

3. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: There is no mention in the specification of "effective amount of an inhibitor of mTOR".

Claim Objections

4. Claims 50 and 51 are objected to under 37 CFR 1.75(c) as being in improper form because they depend from themselves. See MPEP § 608.01(n). Accordingly, the claims not been further treated on the merits.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear; concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1, 8-9, 11, 13, 16, 28, 34-51 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically there is no mention in the specification of inhibitor mTOR". No definition has been provided by the applicant's specification for the term "mTOR", but a definition provided by they examiner (enclosed) is mTOR is a serine/threonine kinase that is activated by Akt and regulates protein synthesis on the basis of nutrient availability. Applicant's specification mentions coating at least a portion of the intravascular implant with a therapeutically effective amount of where the first agent may be rapamycin and a second coating, which may be Tyrosine Kinase. Neither of these are serine/threonine kinase. Serine is a non-essential amino acid with a make up of β-hydroxyalanine; α-α-β – hydroxypropionic acid. $HOCH_2CH(NH_2)COOH$. Tyrosine is also a nonessential amino acid with a different makeup of β-p-hydroxyphenylaline; $C6H_4OHCH_2CHNH_2COOH$. Threonine, which is contained in mTOR, is CH3CH(OH)CH(NH2)COOH that is different from

Tyrosine. Therefore there is not adequate support for mTOR. Additionally there is no mention for the method of an effective amount of the inhibitor mTOR.

6. Claim 35 and 44, 50 contain the trademark/trade name **GLEEVEC.** Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe **a PDGF inhibitor/Imatinib mesylate** and, accordingly, the identification/description is indefinite.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

> only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1, 8-9, 11, 13, 16, 34, 36-42, 45-49 are rejected under 35 U.S.C. 102(e) as being anticipated by Davila et al. 2004/0102758. Davila et al. discloses the invention as claimed comprising : a method for treating a patient by diagnosing the patient as having a vascular disease (inherent) ; coating at least a portion of the intravascular implant with a therapeutically effective amount of an (rapamycin) of mTOR; coating at least a portion of the intravascular implant with a therapeutically effective amount of an inhibitor of PDGF receptor and implanting the intravascular implant in the patient to treat the vascular disease. See sections [0011, PDGF, 0069 which states mTOR inhibitors, 102-103 which specify the use of multiple drugs coated in different layers in conjunction with polymer layers.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 28, 34, 35, 40-41, 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davila et al. in view of Sukhatme 2005/0261283. Davila et al. has been disclosed above with regards to providing more than one drug coating mTOR inhibitors and PDGF inhibitors onto a vascular implant. However Davila et al. does not specify that a PDGF receptor is imatinib mesylate or GLEEVEC (see for example

sections [0073, 0075, 0086, 0087]. It would have been obvious to one having ordinary skill in the art at the time the invention was made to take the invention of Davila et al. and incorporate an inhibitor of PDGF/GLEEVEC© onto a vascular device because Davila states that a variety of drugs may be incorporated onto a stent in the form of a coating/film to minimize or eliminate a biological organisms response to the introduction of medical devices.

11. Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Davila et al. in view of Sukhatme and further in view of Repetto EP 1262153. Davila et al. and Sukhatme have been disclosed above however they do not specify coating, which is performed at the procedure site and before implanting the implant. Repetto teaches that vascular stents may be coated with a pharmaceutical. It would have been obvious to one having ordinary skill in the art at the time the invention was made to perform the coating processes as claimed on site before implanting into the patient because it would provide the necessary concentration and time of drug release for a specific patient.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzette J. Jackson whose work schedule is Monday-Friday 9-6:30 off every other Friday and whose telephone number is 571-272-4751.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Suzette J-J Gherbi
14 December 2005